UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, *et al.* Defendants	Civil Action No. 3:17-01362
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, *et al.* Defendants	Consolidated Case: Civil Action No. 3:17-cv-01665

PLAINTIFFS' RESPONSE TO AMERISOURCEBERGEN DRUG CORPORATION'S MEMORANDUM IN SUPPORT OF MOTION FOR JUDGMENT UNDER RULE 52(C) BASED ON PLAINTIFFS' FAILURE TO PROVE CULPABLE CONDUCT

July 25, 2021

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Code and Regulations

Other Publications

PRELIMINARY STATEMENT

Plaintiffs' evidence overwhelmingly demonstrates that ABDC behaved unreasonably in its distribution of prescription opioids, thus providing the predicate culpable conduct for a finding of public nuisance. Given the dangerous and addictive nature of these drugs, it was necessary for ABDC to control their distribution and to take steps to prevent diversion for illegitimate purposes. ABDC created national policies that purported to provide tools to prevent diversion, through the identification of so-called "suspicious orders," those with indicia of diversion. But these tools were not, in fact, effective in preventing diversion and ABDC did not, in any event, seriously implement them. Its failure to control the supply chain for the dangerous drugs it was distributing was unreasonable and created a public nuisance, when inevitably and predictably, the drugs were diverted. In particular, the evidence shows that ABDC's distribution of prescription opioids was unreasonable because:

- ABDC's program for detecting "suspicious orders" of prescription opioids was not designed to, and could not, detect a significant percentage of orders that were sufficiently unusual in volume, pattern, or frequency to be indicative of diversion;
- ABDC failed to perform due diligence on opioid orders it knew were suspicious to determine if diversion was likely, shipped orders of prescription opioids it knew were suspicious without first ascertaining that those orders were not likely to be diverted, and continued shipping opioids to pharmacies that it knew showed indicia of diversion;
- ABDC failed properly to implement the suspicious order monitoring (SOMs) program that it did have;
- ABDC distributed a total of 36 million dosage units of hydrocodone and oxycodone to pharmacies in Cabell-Huntington, between June, 2002 and December of 2018, the equivalent of 360 doses for every man, woman, and child in the community, an amount that was, in and of itself, unreasonable and could not be explained by changes in the standard of care for treating pain; and
- ABDC knew that its anti-diversion programs were inadequate, and knew the devastating effects of the failure to maintain controls against diversion, but failed to make changes to address the inadequacies; and

- ABDC's failure to detect, investigate, and halt suspicious orders violated the federal Controlled Substances Act ("CSA"), which sets the standard of care for reasonable conduct in the distribution of dangerous narcotics.

This evidence is sufficient to establish ABDC's culpable conduct, and under West Virginia law, liability for public nuisance.

RULE 52(C) LEGAL STANDARD

Plaintiffs incorporate the Legal Standard as set forth in Plaintiffs' Memorandum of Law in Opposition to Defendants' Motions for Judgment on Partial Findings on Causation (Dkt. No. 1469).

THE EVIDENCE

I. ABDC'S NATIONAL POLICIES WERE NOT DESIGNED TO, AND COULD NOT, DETECT SIGNIFICANT QUANTITIES OF SUSPICIOUS ORDERS

The evidence introduced at trial shows that, throughout the time period at issue in this case, ABDC lacked policies that were capable of detecting significant numbers of orders with indicia of diversion – that is, those that were suspicious because of their size, volume, or frequency. This was true of the policies that ABDC maintained before 2007 and was also true of the later policies that ABDC implemented beginning in 2007.

A. ABDC's Pre-2007 Anti-Diversion Policies Were Inadequate to Detect Suspicious Orders

Prior to 2007, ABDC maintained SOMs policies that lacked systematic and objective criteria to identify pharmacy orders that were suspicious and indicative of potential diversion. Indeed, at trial, ABDC admitted that during the 1990's, ABDC order-fillers (who worked in the vault at its distribution centers) had the responsibility for "knowing the orders that they fill and, if they have any suspicion … depending upon what they *feel*, they have an obligation to report it, which resulted in 12,000 phone calls" a year.[1] These employees had no background in compliance

---

[1] 5/13 Trial Tr. (Zimmerman) at 47-48. (Emphasis added).

nor guidance on how to identify potentially suspicious orders and were not equipped to prevent diversion, particularly based on naked observation or instinct.[2]

ABDC set customer thresholds by creating an average volume of sales for different categories of customers and applying a multiplier of three.[3] Until 1998, ABDC was comparing all pharmacies together in one category, taking an average and identifying anything over the average as suspicious, which resulted in large customers getting reported frequently and smaller customers never getting reported, even if the pattern, volume, or frequency of their orders changed dramatically.[4] This system made it difficult, if not impossible, for ABDC to determine if a pharmacy it was supplying had begun to be a locus of diversion.

In 1998, ABDC began comparing the customer to itself, rather than to all other pharmacies.[5] But it set the threshold to flag an order so high that it was unable to detect gradual increases in diversion. For example, if a customer's previous three-month average was 1,000 pills, a pharmacy could order 3,000 pills the next month before ABDC's system would even flag it as suspicious.[6] ABDC's system did not consider the frequency or pattern of orders that should have allowed it to make informed decisions to investigate and cancel certain shipments to its pharmacy customers that the governing regulations defined as suspicious.[7] Moreover, the staggeringly high threshold baseline of three times (or 300%) of a prior 3-month average ensured that few orders

---

[2] 5/13 Trial Tr. (Zimmerman) at 51-52 (order-fillers were cited the "Code of Federal Regulations" as to whether an order is suspicious).

[3] P-00082 at 2 (1999 Bergen Brunswig Regulatory Compliance and Security Services policy document – "monthly average times factor for ARCOS items is presently set by DEA at three times the monthly average"); 5/13 Trial Tr (Zimmerman) at 54, 60-61.

[4] 5/13 Trial Tr. (Zimmerman) at 54.

[5] 5/13 Trial Tr. (Zimmerman) at 54.

[6] 5/13 Trial Tr. (Zimmerman) at 55, 58.

[7] *See* 21 CFR 1301.74(b).

actually were identified.

ABDC's pre-2007 SOMs policies were so inadequate that, in 2007, DEA issued an Immediate Suspension Order against ABDC for its systematic failure to maintain effective controls against diversion. DEA required ABDC to substantially improve its suspicious order monitoring Program,[8] but the new program – known as the Order Monitoring Program, or OMP -- remained inadequate to detect and identify suspicious orders.

B. ABDC's Anti-Diversion Policies from 2007 Forward Remained Inadequate to Detect Suspicious Orders

As result of its settlement with the DEA, ABDC revised certain components of its threshold system. Specifically, its revised threshold system grouped customers by DEA classification (*i.e*. hospital, retail pharmacy, practitioner, or distributor) and subclasses (small, medium, large) based on the total dollar value of prescription sales.[9] ABDC used a national average of each customer group's purchases and, as before, multiplied that average by three to develop a threshold.[10] From 2007 to 2014, ABDC's suspicious order threshold was based on a national average of customers.[11] During that same time period, ABDC's program did not consider a pharmacy's local population or local total sales volume.[12] As a result, suspiciously large orders of opioids in rural areas and smaller cities were virtually invisible to ABDC.

In 2009, ABDC's monthly default thresholds for small accounts ("total monthly dollar volume <$100K") were set for oxycodone at 12,366 and hydrocodone at 18,480.[13] For medium

---

[8] *See infra*, at § A(3)(e); *see also* 5/12 Trial Tr. (Zimmerman) at 228; P-00877.

[9] 5/13 Trial Tr. (Zimmerman) at 54, 223-226; *see also* 5/17 Trial Tr. (Mays) at 203-04; P-00432;

[10] 5/18 Trial Tr. (Mays) at 133 (threshold system 2007-14 was simply times the national average).

[11] 5/18 Trial Tr. (Mays) at 34-35.

[12] 5/17 Trial Tr. (Mays) at 203, 205.

[13] P-00432; 5/13 Trial Tr. (Zimmerman) at 223-224.

accounts ("total monthly dollar volume $100 K-$249,999") the threshold for oxycodone was 24,732 and hydrocodone was 39,960.[14] For large accounts ("total monthly dollar volume >$250K") the threshold for oxycodone was 37,098 and hydrocodone was 55,440.[15]

Under the 2009 default thresholds, a small pharmacy could order 350,000 dosage units of hydrocodone and oxycodone a year without triggering the thresholds and ABDC's order monitoring process.[16] A medium sized pharmacy could order 760,000 dosage units of hydrocodone and oxycodone a year without triggering the thresholds and ABDC's order monitoring process.[17] A large pharmacy could order over a million dosage units of hydrocodone and oxycodone a year without triggering the thresholds and ABDC's order monitoring process.[18] ABDC's inflated thresholds were further eroded by its practice of warning its pharmacy customers that they were approaching their monthly thresholds.[19]

ABDC's revised threshold system did not fix the prior broken system from 1996-2007. Rather, as noted above, the revised system continued to ignore critical information such as local population numbers and total sales volume. This omission is particularly egregious in a SOM system, given that when communities are flooded with a high volume of opioids, the disparity between pills and population increases the incidence of heroin initiation, addiction, and death in that community.[20]

---

[14] *Id.*

[15] *Id.*

[16] 5/13 Trial Tr. (Zimmerman) at 225; *see also* P-00432.

[17] 5/13 Trial Tr. (Zimmerman) at 225; *see also* P-00432.

[18] 5/13 Trial Tr. (Zimmerman) at 226; *see also* P-00432.

[19] Hazewski, 10/25/18 Depo at 123-125.

[20] 7/2 Trial Tr. (Gilligan) at 159, 165.

When coupled with the continuation of its 300% multiplier as a benchmark for an order to even warrant further review, ABDC's revised system continued to permit excessive shipments: under its 2009 default thresholds, even the smallest pharmacies, servicing the smallest communities in the country, could receive tens of thousands of opioid dosage units per month without ever triggering any sort of review, investigation, or analysis. Further, its practice of warning pharmacy customers that they were approaching threshold ensured that its customers could continue to receive high quantities of opioids without ABDC ever identifying orders as suspicious or triggering an investigation inquiry. This resulted in large, sustained volumes of opioid shipments from ABDC across the country.

Simply put, it was unreasonable for ABDC to use criteria for suspicious orders that did not take account of local population size and could not detect changes in ordering practices more gradual than a rapid 300% increase.

C. Mr. Rafalski Established that ABDC Failed to Maintain Effective Controls Against Diversion in Huntington and Cabell County

Mr. Rafalski is a former Drug Enforcement Agency ("DEA") diversion investigator with extensive law enforcement experience relating to the distribution of controlled substances under the Controlled Substances Act ("CSA").[21] Mr. Rafalski testified that there was no evidence in the record that ABDC monitored the overall volume of hydrocodone and/or oxycodone each distributed into Huntington or Cabell County during the relevant time frames of the available data.[22]

Based on his experience, he carefully assessed Defendants' Suspicious Order Monitoring ("SOM") programs and opined that ABDC did not maintain effective control to prevent diversion

---

[21] *See* 5/26/21 Trial Tr. (Rafalski) at 15-16 (position at DEA was "Diversion investigator").

[22] *Id.* at 58-59.

of prescription opioids into the illicit market in Cabell-Huntington.[23] He opined that ABDC's systemic failures were a substantial factor in the diversion of prescription opioids into the illicit market in Cabell-Huntington.[24] He further opined that the orders the Defendants knew or should have known were suspicious were likely to be diverted into the illicit market in Cabell Huntington.[25]

Mr. Rafalski testified regarding six methodologies—two based on an approach endorsed by a United States Court of Appeals, and four based on systems Defendants and other distributors have used—that ABDC could have used to identify suspicious orders (Methods A-F).[26] Applying these to ABDC's customer and due diligence reports, Mr. Rafalski established the numbers of orders Defendants shipped that should have been flagged as "suspicious" under the law and should have triggered due diligence investigations.[27]

Applying "Method B", Mr. Rafalski testified that 3,763,580 or 29.4 percent of the total dosage units of oxycodone and 5,616,380 or 24.8 percent of the total dosage units of hydrocodone sent to Cabell-Huntington should have been flagged by ABDC as suspicious and not shipped before due diligence was conducted.[28]

Mr. Rafalski also testified that application of Methods A and C-F would have revealed even higher numbers of suspicious oxycodone and hydrocodone shipments by ABDC.[29]

---

[23] *Id.* at 110.

[24] *Id.* at 111.

[25] *Id.* at 112-113.

[26] *See id.* at 84-85 (A-D); 93-95 (E-F).

[27] *See id*. at 102:4-10 (review of Defendants' due diligence and customer files); *id.* at 102:18-24 (review of Defendants' suspicious order reporting).

[28] *Id.* at 97-98.

[29] *See id.* at 96-97 (Method A – 11,610,920 or 90.6 percent of total dosage units of oxycodone and 20,621,360 or 91.1 percent of total dosage units of hydrocodone); *id.* 98 (Method C – 10,477,680

Mr. Rafalski's review of ABDC's customer files and documents revealed both the absence of any evidence to dispel the suspicions of any orders that were or should have been flagged, and the presence of an absurdly low number of suspicious order reports actually made by ABDC.[30] ABDC reported just 45 orders as suspicious out of 777,398 transactions with pharmacies in Cabell-Huntington between 2007 and 2018.[31]

Mr. Rafalski opined that based on his education, background, experience, and on his review of ABDC's documents and conduct, including those evidencing ABDC's lack of effective controls to prevent diversion and systemic failure to conduct due diligence, that it was more likely than not that flagged orders regarding which ABDC did not conduct due diligence would be diverted.[32]

II. ABDC Failed to Perform Due Diligence on Suspicious Orders and Shipped Orders to Pharmacy Customers with Knowledge that the Orders Were Suspicious

But even if ABDC had been able to detect suspicious orders, it would have made no difference because its identification of orders as either excessive or suspicious had no bearing on what it decided to ship to its pharmacy customers. Rather, for a time, ABDC shipped all such orders, regardless of any indicators of suspicion.[33] Without any policy to identify or block suspicious orders, the result is an inevitably inflated amount of opioids shipped across the country, including into the Cabell-Huntington area. Even when ABCD in theory implemented a due

---

or 81.8 percent total dosage units of oxycodone and 18,877,140 or 83.4 percent total dosage units of hydrocodone); *id.* at 99-100 (Method D – 8,360,740 or 65.3 percent total dosage units of oxycodone and 15,701,930 or 69.4 percent total dosage units of hydrocodone); *id.* at 100 (Method E – 10,446,280 or 81.5 percent of total dosage units of oxycodone and 21,679,760 or 95.8 percent of hydrocodone); and *id.* (Method F – 12,459,020 or 97.3 percent of total dosage units of oxycodone and 22,582,020 or 99.8 percent of total dosage units of hydrocodone).

[30] *See id.* at 102-103.

[31] *Id.*

[32] *Id.* at 112:22-113:6.

[33] 5/13 Trial Tr (Zimmerman) at 45.

diligence policy, in practice, decisions whether to ship suspicious orders were made by ABDC's sales force, which had every incentive to ship as many orders as possible.

Prior to 2007 any order that exceeded ABDC's threshold calculation was deemed excessive and simply reported to the DEA as an Excessive Order Report.[34] No further action was taken – the order was shipped and no investigation took place. A pharmacy could place orders deemed excessive month after month, and ABDC would simply note the suspicious behavior and ship the drugs, no questions asked.

In December 2005, ABDC implemented an "Excessive/ Suspicious Order Investigation Program" to review the ordering activity of its customers to identify possible excessive or suspicious orders of controlled substances and listed chemicals, but to the extent this review occurred, it only occurred *after* orders were shipped. ABDC did not change its practice of shipping orders identified as excessive before reporting them to the DEA.[35]

Thus, prior to 2007, ABDC did not collect any due diligence information with respect to its customers and orders it received that may have been suspicious, and made no effort to halt any such orders. On May 8, 2007, ABDC finally adopted a policy to block suspicious orders.[36] ABDC's new policy was to hold orders that exceeded a customer's threshold and not ship them, pending review by its national Corporate Security and Regulatory Affairs ("CSRA") investigatory group – CSRA Review.[37] The distribution center could release an order if it felt comfortable releasing based on the knowledge of the customer; if the distribution center did not clear the order,

[34] 5/13 Trial Tr (Zimmerman) at 54, 60-61.

[35] 5/13Trial Tr. (Zimmerman) at 45 (pre-2007, ABDC shipped suspicious orders).

[36] 5/13 Trial Tr. (Zimmerman) at 71; P-26293.

[37] 5/13 Trial Tr. (Zimmerman) at 76 (ABDC OMP, Oct. 2008, if order flagged as suspicious, customer cut off until resolved); 79-82, 222 (ABDC memo, June 2007, customer exceed monthly threshold, reject further sale of like items until customer cleared)

it was sent to corporate for review.[38] Those orders were supposedly not to be shipped unless the suspicion was resolved.[39] The process did not get triggered unless the computer flagged the order.[40] Held orders went into a queue via a messaging system to be reviewed.[41] But the evidence shows that the ABDC's due diligence programs for such review were ineffective, unenforced, and provided no meaningful safeguards that would reduce ABDC's suspicious opioid shipments to its pharmacy customers to prevent diversion.

III. ABDC FAILED TO IMPLEMENT AND CARRY OUT THE DUE DILIGENCE PROGRAMS IT ADOPTED

As part of its OMP as a result of the DEA's 2007 Immediate Suspension Order, ABDC implemented a "Know Your Customer" due diligence program, but failed fully to make use of that program. ABDC implemented it's Know Your Customer due diligence program using its Form 590. ABDC had not been collecting due diligence data prior to 2007 and did not go back and conduct due diligence on existing customers.[42] In July 2016, ABDC launched a formal "CSRA Form 590 Validation Project" to obtain due diligence documentation for every customer authorized to purchase controlled substances.[43] The first phase of this project involved conducting "a full review of every ABDC customer authorized to purchase controlled substances and identify any with deficiencies."[44] After this review was conducted, "a substantial number of customers

---

[38] 5/17 Trial Tr. (Mays) at 215.

[39] 5/17 Trial Tr. (Mays) at 215. *See also* Ed Hazewski, Corporate Security & Regulatory Affairs testified that to thoroughly investigate suspicious orders it was necessary to determine whether or not there was a reasonable explanation for a flag). *See* Hazewski, 10/25/18 Depo at 60.

[40] 5/17 Trial Tr. (Mays) at 216.

[41] 5/18 Trial Tr. (Mays) at 74-76.

[42] 5/14 Trial Tr. (May) at 48.

[43] P-41623.

[44] P-41623.

were identified who will be required to have their 590 documentation updated."[45] However, even though a substantial number of customers needed their due diligence documentation updated, ABDC's sales force's priority was "still the financial performance of your assignment."[46]

ABDC's sales team was responsible for performing on-site investigations for due diligence, was the "eyes and ears" of Regulatory Affairs, and collected information regarding potential red flags.[47] Employing its sales team as a central component of its Know Your Customer program, however, created an obvious conflict of interest that helped make that program toothless.

For instance, in 2011, ABDC's Business Development Manager pushed back on cutting off a customer which had a 100% increase in their oxycodone purchases between August and September with no corresponding rationale for the spike recommending to "re-consider such harsh action."[48] Other personnel chimed in that if ABDC followed through with cutting them off they would lose "a million dollars a month-12 million per year. My numbers can't handle that loss and I don't think ABC would want that type of loss either. ..We stand to lose these 2 customers and send a terrible message to the retail community in the entire region…."[49]

The above email exchange demonstrates that ABDC employees openly acknowledged that they were more concerned about losing sales and protecting customers than preventing diversion and protecting the communities they served.[50] ABDC offered sales representatives bonuses based on sales and sales representatives could lose bonus amounts if a customer left ABDC.[51]

---

[45] P-41623.

[46] P-41623; 5/19/21Trial Tr. (Perry) at 166.

[47] 5/18 Trial Tr. (Mays) at 38; *see also* 5/19 Trial Tr. (Perry) at 91, 94, 103.

[48] P-02504.

[49] P-02504 at 2.

[50] P-02504

[51] Elkins, 11/14/18 Depo at 123-25, 131, (ABDC offered sales representatives bonuses based on

ABDC's local sales executive, Mike Perry, testified regarding an email from Nathan Elkins regarding a summer review of "all accounts with less than $50,000/month in volume" and "for any such accounts that were purchasing a high percentage of controlled substances in relation to their overall TRV, you were directed to have frank conversations reiterating the importance of diversion control and that any red flags caused by their purchasing patterns put them at risk of having controlled substance purchases suspended or limited by ABC."[52] Mr. Perry admitted that ABDC did not have these same frank conversations about diversion control with customers over $50,000.[53]

As described below, ABDC did not apply the due diligence policies it had to chain pharmacies, nor did it apply them to local pharmacies, including local pharmacies in Cabell-Huntington that received extremely high volumes of opioids. The limited utility, implementation, and enforcement of ABDC's Know Your Customer due diligence program meant that it was a wholly ineffective tool to identify problematic customers, stop suspicious orders, or to prevent diversion. ABDC even built financial incentives into that program for its sales team to side-step any legitimate efforts to reduce opioid sales to certain pharmacy customers. The program itself ultimately unfolded as mere lip-service to the DEA, as ABDC's Know Your Customer due diligence records simply did not exist for large swaths of ABDC pharmacy customers in general, and multiple problematic pharmacies in the Cabell-Huntington area, in particular. Without an effective or meaningful due diligence program in place, ABDC's opioid shipments across the country remained at relentlessly high levels even after the 2007 ISO.

---

sales numbers; the higher the number, the more you make) 160-61, 213 (sales representative could lose bonus amounts if customer leaves ABDC; total sales goal figure not adjusted)

[52] 5/19 Trial Tr (Perry) at 148-149; P-41622.

[53] *Id.*

A. ABDC Did Not Apply Its Due Diligence Policies to Chain Pharmacies

ABDC imposed different, even less rigorous rules on its chain pharmacy customers in its Know Your Customer program. Under these rules, ABDC did not apply that program's due diligence requirements to chain pharmacies.[54] Instead of collecting due diligence information from each pharmacy location of a retail chain, ABDC merely created a chain-wide spreadsheet.[55] ABDC even offered pharmacy customers volume-based discount pricing.[56]

For example, Walgreens submitted a single 590 spreadsheet for all of its stores[57]. Thus, ABDC brought in Walgreens stores as customers *en masse*, without conducting due diligence on individual stores – effectively, and impermissibly delegating the responsibility to "Know Your Customer" for each store to the chain pharmacy itself. ABDC went even further in abdicating its due diligence responsibilities and emailed Walgreens the store-specific thresholds.[58]

B. ABDC Did Not Apply Its Due Diligence to Local Pharmacies

The evidence shows that ABDC did not conduct due diligence with respect to local pharmacies, including SafeScript, which was ultimately raided by the police and shut down after ABDC failed to detect diversion there and continued to supply it with large quantities of opioids.

As detailed below, ABDC increased SafeScript's oxycodone thresholds to more than four times their initial level—from 10,600 dosage units before September 2007 to 45,000 dosage units

[54] 5/19 Trial Tr. (Mays) at 38

[55] 5/17 Trial Tr. (May) at 174.

[56] Elkins, 11/14/18 Depo at 77-80.

[57] 6/15 Trial Tr. (Keller) at 142.

[58] Hazewski, 10/25/18 Dep at 124-25. Hazewski testified that Mays was "trying to think of everything we can do to prevent having a bunch of [WAG] orders reported to DEA and held" *Id.* at 138.

per month in June 2009--without meaningful due diligence.[59] ABDC could not produce due diligence documents to justify any of these threshold increases.[60]

Flagged orders from July 2007 show that ABDC set SafeScript's oxycodone threshold at 10,600 doses per month. However, in June 2007, ABDC shipped SafeScript 53,900 dosage units of oxycodone. During its entire relationship with SafeScript, ABDC shipped the pharmacy less than three times the 10,600 threshold just once – in the pharmacy's first month with ABDC, when it purchased 28,700 doses of oxycodone.[61] The persistent failures were clear.

By September 2007, ABDC had increased SafeScript's threshold for Oxycodone Solid pills from 10,600 to 30,000 dosage units per month.[62] By July 2009, the monthly threshold was increased to 45,000 dosage units of Oxycodone Solids.[63] Indeed, from ABDC's transactional data, SafeScript Pharmacy #6 received an average of 35, 551 dosage units of oxycodone each month from January 2006 through February 2012, totaling 2,630,740 dosage units of oxycodone.[64]

In 2009, Mr. Perry replied to an inquiry regarding SafeScript by the Lockbourne Manager of Regulatory Compliance advising, "this account has always purchased a high volume of Controls to total sales. We have made adjustments to the Thresholds in the past due to this being the primary business at this account."[65]

---

[59] P-16639; *see also* 5/18 Trial Tr. (Mays) at 78-87.

[60] P-16639 (illustrates SafeScripts' threshold increases). ABDC's discovery responses were entered into evidence and only consisted of several pages, none of which included justification for the countless increases in threshold which SafeScript received. *See* P-23655.

[61] P-16639.

[62] P-44766 at Row 470.

[63] P-44766 at Row 1647.

[64] P-43225.

[65] P-01655; *see also* 5/19 Trial Tr (Perry) at 124-125, 127-128.

In June 2011, ABDC's Order Monitoring Program flagged 24 SafeScript orders of oxycodone for exceeding its threshold.[66] On July 29, 2011, Mr. Perry requested an oxycodone threshold increase. Although the threshold review form specifies that "exceeding the established threshold does not in itself justify a threshold increase in all cases," the justification for increasing the threshold was that the customer "has had issues with them exceeding the thresholds."[67] Mr. Perry admitted that there was no reason stated for the increase to the threshold.[68]

Notwithstanding the fact that Mr. Perry submitted a threshold request with no further justification than the customer had issues with exceeding thresholds, the request for the threshold increase was approved.[69] Ed Hazewski responded, "The customer has been adjusted and is now set at the maximum they can receive of this product. Their CS ratio is 86% of their overall purchases."[70]

For comparative purposes, ABDC noted in January 2009 that the "average retail customer in our customer base has a CS ratio of about 12%."[71] The unjustified increase of SafeScript's threshold to an 86% CS ratio clearly establishes that ABDC was not following its policy that "thresholds will remain firm for the appropriate customer size. No orders surpassing the threshold

---

[66] P-16639.

[67] P-16651; *see also* 5/19 Trial Tr (Perry) at 129-131.

[68] 5/19 Trial Tr. (Perry) at 140-141.

[69] P-16642; *see also* 5/19 Trial Tr (Perry) at 142.

[70] P-16642; *see also* 5/19 Trial Tr (Perry) at 142. A controlled substance ration ("CS ratio") is the total sales amount of controlled substances over the total sales amount. 5/19 Trial Tr (Perry) at 77-78.

[71] P-00432.

will be released and no thresholds will be changed unless there is a change in the customer's ratio of CS."[72]

Mr. Perry had been trained that a high controlled substance ratio could be a concern and was a question on the 590 form.[73] Mr. Perry admitted that at the time the threshold was adjusted, Regulatory Affairs knew the controlled substance ratio was high, that more than one distributor was being used, and that the pharmacy was filling prescriptions for pain clinics.[74]

When Mr. Perry forwarded via email the Request for Threshold Review, he also forwarded an email from SafeScript which noted "Troublesome Drugs" – oxycodone and oxycontin and identified three prescribers including doctors Deleno Webb and Philip Fisher.[75] Mr. Perry testified that he had no knowledge regarding any issues with Dr. Webb.[76] He testified that he provided the names because they had asked for the information but he had no idea what Regulatory Affairs did with the names.[77] He did not know that Dr. Webb was a psychiatrist.[78]

---

[72] P-00432.

[73] 5/19 Trial Tr (Perry) at 98.

[74] 5/19 Trial Tr. (Perry) at 140-145.

[75] P-16651; 5/19 Trial Tr. (Perry) at 131. In 2005, Dr. Webb was banned by the West Virginia Worker's Compensation Commission from receiving payment for treating injured workers and surrendered his medical license in 2017. 6/15 Trial Tr. (Keller) at 181-182. Dr. Fisher's license to practice osteopathic medicine was suspended in 2011 and was the subject of a number of board actions pertaining to his prescribing practices as relating to the deaths of at least seven patients. 6/15 Trial Tr. (Keller) at 134.

[76] 5/19 Trial Tr. (Perry) at 131.

[77] 5/19 Trial Tr. (Perry) at 133.

[78] 5/19 Trial Tr. (Perry) at 142. Dr. Webb was also a pain management doctor. 6/15 Trial Tr. (Keller) at 133.

SafeScript was raided by the police and closed in February 2012, approximately 6 months after ABDC increased its threshold levels to the maximum.[79] Mr. Perry was unaware of anyone from Regulatory Affairs ever going to SafeScript from 2004 until the time it was closed.[80]

In total, from July 2007 until July 2011, the OMP flagged at least 1,171 SafeScript orders for exceeding thresholds, including 775 orders of opioids. However, ABDC only reported 41 SafeScript orders to the DEA as suspicious, including just 16 opioid orders. Although ABDC internally flagged 617 SafeScript orders of oxycodone as suspicious, it only reported 13 orders to the DEA, on just 3 days: March 28, 2008, December 31, 2009, and January 30, 2010.[81]

SafeScript was not the only local pharmacy for which ABDC failed to conduct due diligence. In 2015, the DEA conducted an audit of the ABDC Lockbourne distribution center that serves Cabell-Huntington.[82] During the audit, the DEA diversion investigator requested copies of the due diligence files for several customers, including McCloud and Drug Emporium.[83] ABDC could not locate the files as the McCloud "Lawtrac matter is empty" and "requesting hard file from Iron Mountain – file not found."[84] Similarly, ABDC found that the Drug Emporium "Lawtrac matter is empty."[85] Whatever ABDC's policies may have looked like on paper, they were not actually applied in the field in the Cabell-Huntington community.

---

[79] 5/19 Trial Tr. (Perry) at 145.

[80] 5/19 Trial Tr. (Perry) at 129-130.

[81] P-166639a.

[82] P-17140; 5/17 Trial Tr. (May) at 167:1-169:10.

[83] P-17140; 5/17 Trial Tr. (May) at 169:11-19.

[84] P-17140; 5/17 Trial Tr. (May) at 170:14-19. Lawtrac was ABDC's electronic databased which contained its customer's due diligence information prior to its current iteration known as Archer. 5/17 Trial Tr. (May) at 166. Iron Mountain is where ABDC stores its hard copy documents. 5/17 Trial Tr. (May) at 174-175.

[85] P-17140; 5/17 Trial Tr. (May) at 171:6-8.

IV. ABDC DISTRIBUTED UNREASONABLE QUANTITIES OF OPIOIDS IN CABELL-HUNTINGTON

The evidence shows that ABDC distributed unreasonable quantities of opioids to its customers in Cabell-Huntington. The evidence also shows that this excessive distribution was the direct result of ABDC's failures to detect, investigate, and halt suspicious orders in order to prevent diversion. The enormous quantities of opioids that ABDC distributed were, moreover, clear signs that the opioids ABDC was selling were being diverted. There were simply not enough people living in the Cabell-Huntington community for the quantity of opioids to be used exclusively for legitimate purposes.

Between June 2002 and December 2018, ABDC distributed 36 million dosage units of hydrocodone and oxycodone to pharmacies in Cabell-Huntington, a community of 100,000 people.[86] Between 2006 and 2014, ABDC's monthly average shipments of oxycodone to Cabell-Huntington chain and retail pharmacies was 10,743 dosage units compared to its national average of 5,036 units.[87]

In January 2006, the national average shipments from ABDC of oxycodone to chain and retail pharmacies was 3,424; to West Virginia it was 4,764; and to Cabell Huntington it was 7,569 – 220% of the national average.[88] In January 2010, the national average shipments of ABDC of oxycodone to chain and retail pharmacies was 4,683 units; to West Virginia was 6,849 units; and to Cabell-Huntington it was 15,186 units – 3.5 times the national average.[89]

---

[86] P-44711_00021; *see also* 5/18 Trial Tr. (Mays) at 115-117.

[87] P-43225; *see also* 5/10 Trial Tr. (McCann) at 115-116.

[88] P-43225; *see also* 5/10 Trial Tr. (McCann) at 117-118.

[89] P-43225; *see also* 5/10 Trial Tr. (McCann) at 116-117, 118.

ABDC's three times threshold multiplier and broad customer groupings meant that orders that should have raised suspicions would not be detected by the OMP. ABDC's shipments to SafeScript, McCloud Family Pharmacy, Drug Emporium, Medical Park, Fruth Pharmacy, andWalgreens #11977, in particular, demonstrate the extraordinary and unreasonable volume of pills shipped into the area.

During January 2006, the national average sales of oxycodone were 3,424 a month.[90] During that same month, ABDC shipped 38,100 dosage units to SafeScript #6.[91] The national average in November 2006 was 3,649 and the amount shipped to SafeScript #6 was 56,700.[92] Steve Mays admitted that the amounts shipped to SafeScript were clearly in excess of the national average.[93]

The average shipment of oxycodone to SafeScript by ABDC from 2006 to 2012 was 35,551 – 600% more than the national average.[94] This would amount to 426,000 dosage units of oxycodone a year to SafeScript from ABDC compared to ABDC's national average of 60,000.[95] Between January 2006 and February 2012, ABDC sold and shipped 2,630,740 oxycodone dosage units to SafeScript in Cabell-Huntington.[96]

Between January 2006 and December 2014, the average oxycodone shipment from ABDC to McCloud Family Pharmacy was 18,028 – 260% higher than the national average.[97] The

[90] P-43225; *see also* 5/18 Trial Tr. (Mays) at 121.

[91] *Id.*

[92] *Id.*

[93] *Id.* at 122.

[94] P-43225; *see also* 5/10 Trial Tr. (McCann) at 119.

[95] P-43225; *see also* 5/10 Trial Tr. (McCann) at 119-120.

[96] P-43225.

[97] P-43225; *see also* 5/10 Trial Tr. (McCann) at 120.

shipments of oxycodone from ABDC to McCloud Family Pharmacy steadily increased from 4,300 in January 2006 to 24,500 in January 2010.[98] In March of 2011, the shipments from ABDC to McCloud Family Pharmacy reached 39,900.[99] Between January 2006 and December 2014, ABDC sold and shipped 1,946,980 oxycodone dosage units to McCloud Family Pharmacy in Cabell-Huntington.

Between January 2006 and December 2014, the average oxycodone shipment from ABDC to Drug Emporium was 13,505 dosage units.[100] The shipments of oxycodone from ABDC to Drug Emporium increased from 7,100 in January 2006 to 17,100 in January 2010.[101] In March 2010, the shipments from ABDC to Drug Emporium reached 24,500.[102] Between January 2006 and December 2014, ABDC sold and shipped 1,458,500 oxycodone dosage units to Drug Emporium in Cabell-Huntington.[103] By December 2009, ABDC had set Drug Emporium #1's thresholds for both drugs at about double the order volumes that had raised suspicions in 2007: 55,440 per month for hydrocodone and 40,000 per month for benzodiazepine.[104] With Drug Emporium #1's thresholds set far above the level that had raised suspicions, and no other program for detecting suspicious orders, ABDC would not have detected, investigated, or reported orders that could be suspicious.

---

[98] P-43225.

[99] P-43225.

[100] P-43225; *see also* 5/10 Trial Tr. (McCann) at 121.

[101] P-43225.

[102] P-43225.

[103] P-43225.

[104] P-44766.

Between January 2006 and May 2012, the average oxycodone shipment from ABDC to Medical Park Pharmacy was 14,807 dosage units.[105] The shipments of oxycodone from ABDC to Medical Park Pharmacy increased from 2,000 in January 2006 to 19,900 in January 2010.[106] In March 2010, the shipments from ABDC to Medical Park Pharmacy reached 25,700.[107] Between January 2006 and May 2012, ABDC sold and shipped 1,140,160 oxycodone dosage units to Medical Park Pharmacy in Cabell-Huntington.[108]

Between January 2006 and December 2009, the average oxycodone shipment from ABDC to Fruth Pharmacy #5 was 11,525 dosage units.[109] The shipments of oxycodone from ABDC to Fruth # 5 increased from 8,600 in January 2006 to 10,200 in December 2009.[110] In December 2008, the shipments from ABDC to Fruth #5 reached 17,400.[111] Between January 2006 and December 2009, ABDC sold and shipped 553,200 oxycodone dosage units to Fruth #5 in Cabell-Huntington.[112]

Between January 2006 and December 2014, the average oxycodone shipment from ABDC to Fruth #12 was 10,363 dosage units.[113] The shipments of oxycodone from ABDC to Fruth #12 increased from 10,400 in January 2006 to 12,300 in December 2009.[114] In April 2008, the

---

[105] P-43225; *see also* 5/10 Trial Tr. (McCann) at 121.

[106] P-43225.

[107] P-43225.

[108] P-43225.

[109] P-43225; *see also* 5/10 Trial Tr. (McCann) at 121.

[110] P-43225.

[111] P-43225.

[112] P-43225.

[113] P-43225; *see also* 5/10 Trial Tr. (McCann) at 121.

[114] P-43225.

shipments from ABDC to Fruth #12 reached 16,400.[115] Between January 2006 and December 2009, ABDC sold and shipped 497,400 oxycodone dosage units to Fruth #12 in Cabell-Huntington.[116]

Between January 2006 and December 2014, the average oxycodone shipment from ABDC to Fruth #2 was 7,256 dosage units.[117] The shipments of oxycodone from ABDC to Fruth #2 increased from 4,700 in January 2006 to 12,200 in December 2009.[118] Between January 2006 and December 2009, ABDC sold and shipped 348,300 oxycodone dosage units to Fruth #2 in Cabell-Huntington.[119]

Between January 2006 and December 2014, the average oxycodone shipment from ABDC to Fruth #11 was 4,915 dosage units.[120] Between January 2006 and December 2009, ABDC sold and shipped 235,900 oxycodone dosage units to Fruth #11 in Cabell-Huntington.[121]

Between April 2013 and December 2014, the average oxycodone shipment from ABDC to Walgreens #11977 was 11,205 dosage units.[122] The shipments of oxycodone from ABDC to Walgreens #11977 increased from 4,100 in April 2013 to 15,300 in December 2014.[123] During that same time period, ABDC sold and shipped 235,300 oxycodone dosage units to Walgreens #

[115] P-43225.

[116] P-43225.

[117] P-43225; *see also* 5/10 Trial Tr. (McCann) at 121.

[118] P-43225.

[119] P-43225.

[120] P-43225; *see also* 5/10 Trial Tr. (McCann) at 121.

[121] P-43225.

[122] P-43225; *see also* 5/10 Trial Tr. (McCann) at 121.

[123] P-43225.

11977.[124]

The average monthly oxycodone purchases from ABDC from its customers SafeScript, McCloud Family Pharmacy, Drug Emporium, Medical Park Pharmacy, the four Fruth Pharmacies, and Walgreens, is in excess of a hundred thousand oxycodone pills every month in Cabell-Huntington pharmacies.[125] The numbers for ABDC's sales of hydrocodone to the local Cabell-Huntington pharmacies follow a similar magnitude both in gross numbers and compared to the national average.[126] The total quantity of opioids ABDC shipped into Cabell-Huntington month after month could not have been reasonable.

V. ABDC Knew that Its Anti-Diversion Programs Were Inadequate, and Knew the Devastating Effects of the Failure to Maintain Controls against Diversion, But Failed to Make Changes

A. The DEA's Told ABDC about Flaws in Its Program, but ABDC Consistently Ignored This Regulatory Guidance

The evidence elicited at trial shows that the DEA communicated specific flaws in ABDC's diversion control programs throughout the years. ABDC's brief, however, downplays the evidence relating to (1) the DEA's Distributor Initiative Meetings, (2) Enforcement Actions against ABDC, and (3) the Dear Registrant Letters sent to ABDC, all of which provided bright line guidance related to ABDC's regulatory obligations and responsibilities to maintain effective controls to prevent diversion. As explained below, ABDC's response to this guidance was to continue to maximize profits through excessive levels of opioid shipments to its customers. ABDC further argues that, far from pointing out ABDC's inadequacies, DEA actually approved its diversion control programs. The evidence shows, however, that this did not occur, and could not have

[124] P-43225.

[125] P-43225; *see also* 5/18 Trial Tr. (Mays) at 123.

[126] *See* P-43225.

occurred because DEA does not approve individual SOM systems. On the contrary, ABDC's failures, over the course of years, to heed DEA's consistent message about the failures of its SOM programs demonstrates the unreasonableness of ABDC's conduct with respect to the distribution of opioids.

1. The DEA Did Not Approve ABDC's Diversion Control Program

ABDC attempts to justify sidestepping the DEA's guidance by arguing the DEA had approved its SOM system in 1998. Trial testimony and documentary evidence, however, indicate no such approval was ever given.

The DEA does not approve or endorse SOM systems.[127] Plaintiffs' witness, Joe Rannazzisi, a retired DEA special agent and Deputy Assistant Administrator for the Office of Diversion Control,[128] testified that a DEA inspection does not enable DEA to determine a SOM system's effectiveness.[129] He further testified that the DEA did not have a SOM approval process and, in fact, communicated the fact that it did not approve SOM programs for registrants.[130] Mr. Rannazzisi explained that the reason it is the registrant's obligation to design and operate a system (rather than the DEA) is because:

> only the registrant knows or can develop a system that conforms to their business plan, to their customer base. DEA can't do that. DEA doesn't know what their customer base is. Doesn't know what their business plan is. Doesn't know how they process orders. Only the registrant could do that.[131]

ABDC's repeated claims that the DEA approved the Bergen Brunswig 1998 diversion

---

[127] Prevoznik, 4/18/19 Depo at 752.

[128] 6/7 Trial Tr. (Rannazzisi) at 162, 165.

[129] 6/8 Trial Tr. (Rannazzisi) at 178-79.

[130] *Id.* at 182, *see also* 6/9 Trial Tr. (Rannazzisi) at 76 (has seen no document that would lead defendants to believe DEA approved their SOM systems before 2005); 220 (DEA did not approve SOM programs during or before tenure); 238 (told in 2005 that DEA not approve SOMs).

[131] 6/10Trial Tr. (Rannazzisi) at 73.

control program ignores the narrow context of such approval. The DEA merely approved the change in mechanism by which ABDC would communicate suspicious orders from telephone calls to facsimile.[132] The language must be interpreted in light of the express purpose of the communication—an interpretation buttressed by DEA's policy of not approving registrants' anti-diversion programs.

Further, in 2007, the DEA advised counsel for ABDC that the Settlement and Release Agreement relating to the OSC/ISO did "not approve or endorse a particular system to identify and disclose suspicious orders."[133] ABDC accordingly has no legitimate basis to ignore the DEA's repeated guidance on its regulatory obligations and responsibilities to maintain effective controls to prevent diversion.

2. The 2000 Memorandum of Understanding Evidenced ABDC's Failure to Maintain Effective Controls to Prevent Diversion

As far back as 2000, ABDC received direct communications from the DEA that indicated ABDC's SOM system did not adequately provide effective controls to prevent diversion. Specifically, in 2000, the DEA and ABDC entered into a Memorandum of Understanding, which alleged ABDC's failure to "provide effective controls and procedures to guard against theft and diversion of controlled substances required by 21 CFR 1301.71(a)" at the Columbus Lockbourne facility which services Cabell-Huntington.[134]

---

[132] AM-WV-00781 at 7 ("Reference is made to your recent letter in which you requested that Bergen Brunswig be permitted to replace its current telephonic reporting of suspicious orders with a daily report transmitted by facsimile. We have reviewed your proposal and feel that it could be a viable alternative to the current system."); *see also* 5/13 Trial Tr. (Zimmerman) at 179.

[133] P-00521; 5/13 Trial Tr. (Zimmerman) at 217-218.

[134] P-00324_00001; *see also* Cherveny, 11/9/18 Depo. at 262-67.

3. The 2005 Distributor Initiative Meeting Provided Regulatory Guidance to ABDC that ABDC Ignored

In 2005, ABDC attended a meeting with the DEA in which the DEA provided specific guidance to ABDC on its regulatory obligations and responsibilities to maintain effective controls against diversion. ABDC, however, ultimately decided to largely ignore that guidance by attempting to frame it as related to internet pharmacies, only.[135] As the trial testimony and documentary evidence show, however, that guidance actually described key deficiencies in ABDC's SOM system and key components of an effective system designed to prevent diversion that ABDC rejected.

Specifically, on August 10, 2005, the DEA held a "Distributor Initiative Meeting" with ABDC.[136] During this meeting, the DEA communicated to ABDC that it had a duty to report suspicious orders when discovered.[137] The DEA also advised ABDC that "reporting a suspicious order to DEA does not relieve a distribution [sic] of the responsibility to maintain effective controls."[138] The DEA wanted to make sure that ABDC understood what their obligations were and to make appropriate corrections to the system ABDC was operating.[139] Mr. Rannazzisi testified:

> The reason for the distributor initiative meetings because we weren't getting suspicious orders. We weren't getting the suspicious orders that basically pinpointed or was a pointer system to potential diverters. What we were getting was excessive purchase reports and, and the like of the excessive purchase reports which are not suspicious orders.[140]

---

[135] *See* ABDC's Brief, at p. 14-18.

[136] 6/8 Trial Tr. (Rannazzisi) at 60.

[137] P-09112 at 9; *see also* 5/12 Trial Tr. (Zimmerman) at 199-200.

[138] P-09112 at 9; *see also* 5/12 Trial Tr. (Zimmerman) at 202.

[139] 6/8 Trial Tr. (Rannazzisi) at 63.

[140] 6/8 Trial Tr. (Rannazzisi) at 103.

Mr. Rannazzisi's testimony is bolstered by Michael Mapes, who also testified that the DEA was "looking for reports that the wholesalers had reviewed, not just with a raw number of drugs that were ordered but reviewed it and determined that it was suspicious."[141] Mr. Mapes further testified that he did not recall the DEA making a distinction between retail chain pharmacies and independent pharmacies during the distributor briefings.[142] He also testified that he "was expecting that over time they would use the same procedures for all the pharmacies that they were dealing with to be certain that there wasn't a problem that they wouldn't see without the extra due diligence."[143] He testified that the distributors were to be looking for "an internet pharmacy or any pharmacy that was selling drugs for other than legitimate purpose" such as a pill mill.[144]

The actual written materials provided to ABDC at the meeting further evidence the broad application of the guidance and directly contradicts ABDC's position that it only applied to internet pharmacies. Specifically, during the meeting, the DEA provided Steve Mays a binder full of written materials, which included a PowerPoint presentation, and case law regarding a distributor's obligations to maintain effective controls to prevent diversion.[145] Among the presentation slides was a summary note that specifically states, "Not limited to Internet pharmacies."[146] The case law given to ABDC also included *Direct Sales, Co., Inc. v. United States*, 319 U.S. 703(1943) and *United States v. Moore,* 651 F.3d 30 (D.C. Cir. 2011), aff'd sub nom. *Smith v. United States,* 568

---

[141] Mapes, 7/11/2019 Depo. at 202-203.

[142] Mapes, 7/11/2019 Depo. at 217.

[143] Mapes, 7/11/2019 Depo. at 217.

[144] Mapes, 7/11/2019 Depo. at 217.

[145] 5/17 Trial Tr. (May) at 179-181; *see also* P-08813.

[146] P-08813, at P-08813_00012.

U.S. 106, 133 S. Ct. 714, 184 L. Ed. 2d 570 (2013),both describing specific distributor obligations, and both decided long before internet pharmacies ever existed.[147]

ABDC's decision to couch the Distributor Initiative Meeting guidance as applicable to internet pharmacies only is accordingly not supported by the evidence elicited at trial. Rather, such evidence points to the fact that ABDC was given direct guidance from the DEA regarding identifying and reporting suspicious orders that ABDC simply ignored. Ignoring these guidelines (which aimed to help distributors identify and report suspicious orders) accordingly allowed ABDC to maintain its high shipping volume without any meaningful guardrails in place.

4. The "Dear Registrant" Letters Provided Regulatory Guidance to ABDC that ABDC Ignored

During 2006 and 2007, the DEA sent three letters to registrants across the country, including ABDC, outlining its legal obligations to conduct due diligence, report suspicious orders, and avoid filling suspicious orders.[148] The September 2006 letter was not a new interpretation of the CSA and was consistent with prior DEA guidance.[149] ABDC chose to ignore the DEA guidance in these letters in order to continue to maintain its high shipping volume throughout the country without any meaningful guardrails in place.

---

[147] P-08813, at P-08813_00023, 00026.

[148] P-00032; *see also* 6/8 Trial Tr. (Rannazzisi) at 115-16.

[149] *Id.* at 121; *see also* Hartle 7/31/18 Dep. at 160-64 (Sept. 2006 Rannazzisi letter "was mostly a confirmation or a reiteration of the regulations, which McKesson knew…. So not significant changes that I'm aware of."; accurate on law); *see also* Prevoznik, 4/18/19 Depo at 761 (nothing in September 2006 Joe Rannazzisi letter is new), 661-65 (NWDA guidelines, 1990's, report suspicious order immediately; after-the-fact monthly printout insufficient), 695-96 (1996 DEA DIM, registrants who fill reported suspicious orders are jeopardizing public health and safety), *see also* Prevoznik, 5/17/19 Depo at 810-11 (DEA 1984 Gitchel ltr.—monthly report of after-the-fact sales not satisfy reporting duty; reporting "orders" means prior to shipment), 933-34 (Rannazzisi letters did not change the obligations of registrants); 6/8 Trial Tr. (Rannazzisi) at 121.

The September 27, 2006 letter was sent to all distributors and manufacturers after the Distributor Initiative Meetings and "reinforces both what was in the distributor initiative, and it provides information concerning obligations under the Controlled Substances Act relating to suspicious order monitoring."[150] The DEA's September 2006 letter provided very specific guidance on the characteristics often displayed by pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose and provided a list of questions a distributor investigating a suspicious order might ask. Specifically, the DEA identified the following characteristics:

1. Ordering excessive quantities of a limited variety of controlled substances (e.g., ordering only phentermine, hydrocodone, and alprazolam) while ordering few, if any, other drugs

2. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered

3. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs

4. Ordering the same controlled substances from multiple distributors.[151]

[150] 6/8 Trial Tr. (Rannazzisi) at 116.

[151] P-00032_00011. The DEA further offered lines of inquiry a distributor seeking to determine whether a suspicious order is indicative of diversion may wish to inquire about from the ordering pharmacy, including, *inter alia,* (1) percentage of controlled substance business; (2) compliance with laws of every state in which it is dispensing controlled substances; (3) is the pharmacy soliciting buyers of controlled substances via the internet or associated with an internet site; (4) does the pharmacy or affiliated internet cite offer to facilitate the acquisition of a prescription for a controlled substance form a practitioner with whom the buyer has no pre-existing relationship; (5) does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or a bona-fide doctor-patient relationship; (6) are the prescribing physicians licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped; (7) are one or more practitioners writing a disproportionate share of the prescriptions being filled by the pharmacy; (8) does the pharmacy offer to sell controlled substances without a prescription; (9) does the pharmacy charge reasonable prices for controlled substances; does the pharmacy accept insurance payment for purchases of controlled substances made via the internet. *Id.* The DEA specifically noted "these questions are not all-inclusive; nor will the answer to any of these questions necessarily determine whether a suspicious order is

The DEA letter advised that a distributor could not rely on a customer's registration as a substitute for performing due diligence.[152]

ABDC admitted that it received the September 2006 letter.[153] In that letter, Mr. Rannazzisi advised:

> DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion. Moreover, all registrants, manufacturers, distributors, pharmacies, and practitioners, share responsibility for maintaining appropriate safeguards against diversion. Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm. Accordingly, DEA will use its authority to revoke and suspend registrations in appropriate cases.
>
> …
>
> Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.
>
> …
>
> In a similar vein, given the requirement under Section 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances.
>
> …
>
> Again, to maintain effective controls against diversion as Section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.[154]

---

indicative of diversion to other than legitimate medical channels. Distributors should consider the totality of the circumstances when evaluating an order for controlled substances …" *Id.*

[152] *Id.* at 118-19.

[153] 5/12 Trial Tr. (Zimmerman) at 213.

[154] *Id.* at 117-19 (reading from P-00032).

The DEA's February 7, 2007 and December 27, 2007 letters again reminded distributors that in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid *filling* suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.[155] The December 2007 letter further noted: "[f]iling a monthly report of completed transactions (*e.g.*, "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders.[156] The DEA also told ABDC in letters and briefings that "Excessive Order Reports" (which all three Defendants were sending to the DEA) were not equivalent to suspicious order reports.[157]

The DEA's December 2007 letter also emphasized:

> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributors. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviated from the normal pattern of what pharmacies generally order.[158]

The DEA further advised that "registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical,

---

155 Among other guidance, the DEA's December 27, 2007, letter also instructed registrants to review the final order issued by the DEA in the matter of *Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007), regarding their legal obligations to report suspicious orders. *See* P-02027; *see also* 6/8 Trial Tr. at 151-52 (DEA's 2007 *Southwood* decision, know-your-customer duty, red flags of diversion; no-ship duty).

156 P-00032; 5/13 Trial Tr. (Zimmerman) at 39-40.

157 6/7 Trial Tr. (Rannazzisi) at 228, 229-30, 231, and 233.

158 P-02027; *see also* 6/8Trial Tr. (Rannazzisi) at 145 (formula-based SOM may miss suspicious orders)

scientific, and industrial channels, may be failing to maintain effective controls against diversion."[159] ABDC admitted that the December 2007 letter provided guidance that when looking for suspicious orders, a distributor should look for ordering patterns from a particular customer and should also compare the ordering patterns of a particular customer throughout the relevant segment of the regulated industry.[160]

Again, ABDC ignored these clear directives from the DEA which aimed to strengthen its ability to maintain effective controls to prevent diversion and lower its total shipping volume. The December 2007 letter specifically provided notice that any prior implicit or explicit suggestions that the DEA had approved systems in the past were revoked.[161] The letter also reiterated that the DEA did not approve or otherwise endorse any specific system of reporting suspicious orders.[162] Notably, ABDC failed to contact Rannazzisi or the DEA to resolve any purported confusion with these points.[163]

ABDC's decision to ignore the clear and repeated regulatory guidance of the "Dear Registrant Letters" is indefensible. When provided specific and concrete information as to the critical flaws of its SOM system, it simply buried its head in the sand. The result is an intentionally weakened and toothless SOM system which fell far short of what the DEA considered to be effective controls to prevent diversion. Such a weakened and toothless system accordingly played no meaningful role in reducing ABDC's overall opioid shipping volume throughout the country.

---

[159] P-00032; 5/13 Trial Tr (Zimmerman) at 44-45.

[160] 5/12 Trial Tr. (Zimmerman) at 41, 44.

[161] P-00032 at 3; 5/13 Trial Tr (Zimmerman) at 38-39.

[162] P-00032 at 3; 5/13 Trial Tr (Zimmerman) at 38.

[163] 5/12/ Trial Tr (Zimmerman) at 220; 5/13 Trial Tr (Zimmerman) at 43. Nor did Zimmerman communicate his disagreement with the Rannazzisi letter during his frequent discussions with the DEA in resolving an ISO in 2007. 5/12 Trial Tr. (Zimmerman) at 231.

5. The 2007 Order to Show Cause and Immediate Suspension Order Against ABDC Further Put ABDC on Notice that Its Systems Were Inadequate to Maintain Effective Controls to Prevent Diversion

In a clear signal that ABDC's SOM system failed to maintain effective controls to prevent diversion, the DEA filed an Order to Show Cause and Immediate Suspension Order ("OSC/ISO") against ABDC on April 19, 2007.[164] The OSC/ISO immediately stripped ABDC's Orlando, Florida facility of its license to distribute controlled substances.[165] The OSC/ISO identified the conduct that the DEA believed violated the CSA to include "notwithstanding the information provided to respondent after the August 10, 2005 meeting … Respondent sold over 5.2 million dosage units of hydrocodone to pharmacies that bore the characteristics that DEA described in the August 10th meeting."[166] In 2005 and 2006, ABDC continued to distribute massive volumes of hydrocodone to internet pharmacies in Florida, in clear disregard of the warnings provided to it by the DEA via the distributor's initiative meetings and the September 2006 "Dear Registrant" letter.[167]

Mr. Rannazzisi testified the failures of ABDC's systems that lead to the OSC and ISO were a total breakdown throughout ABDC's national SOM system.[168] The conduct at issue included allowing the diversion of hundreds of thousands of dosage units into the illicit market.[169] The huge volumes of pills ordered from the internet pharmacies went all over the country and were not

---

[164] 6/8 Trial Tr. (Rannazzisi) at 58-59; P-00049.

[165] *See* P-00049.

[166] *Id.* at 60-61; P-00049 at 3.

[167] P-00049.

[168] 6/8 Trial Tr. (Rannazzisi) at 67.

[169] 6/8 Trial Tr. (Rannazzisi) at 70-72.

geographically limited.[170] By their nature, internet pharmacies, which shipped opioids to any location, would have provided opioids across the United States, including West Virginia.[171]

The DEA and ABDC entered into a Settlement and Release Agreement on June 22, 2007 ("Settlement Agreement") in relation to the conduct alleged in the OSC/ISO.[172] The "covered conduct" in the Settlement included:

> The alleged failure of AmerisourceBergen to maintain adequate controls against diversion of controlled substances, on or prior to May 22nd 2007, at the Orlando facility and **all other distribution facilities** controlled by AmerisourceBergen, with respect to all sales of Automation of Reports and Consolidated Orders System reportable controlled substances, benzodiazepines and phentermine; and, three, the alleged failure to detect and report suspicious orders of sales of the controlled substances set forth in Subsection I(3)(ii) of this agreement as required by 21, C.F.R., 1301.74(b).[173]

The controlled substances mentioned in the settlement included opioids.[174] The Settlement Agreement covered all distribution centers including the Lockbourne, Ohio location that shipped opioids to Cabell-Huntington.[175] As a result, ABDC finally agreed to maintain a compliance program to detect and prevent diversion of controlled substances.[176] Mr. Rannazzisi further testified that while the DEA did not initiate additional enforcement actions against ABDC, that "doesn't mean they were compliant."[177]

---

[170] 6/7 Trial Tr. (Rannazzisi) at 191-92.

[171] 6/7 Trial Tr. (Rannazzisi) at 169 (internet trafficking was taking over a lot of the pharmaceutical issues and diversion that was happening in the United States across the country).

[172] 6/8 Trial Tr. (Rannazzisi) at 68; P-00009.

[173] 6/8 Trial Tr. (Rannazzisi) at 68-69; P-00009 at 2 (emphasis added).

[174] 6/8 Trial Tr. (Rannazzisi) at 69.

[175] 5/12 Trial Tr. (Zimmerman) at 226-227.

[176] *Id.* at 227-28.

[177] 6/8 Trial Tr. (Rannazzisi) at 72.

B. The FTI Consulting Report Highlighted Critical Shortfalls of ABDC's Order Monitoring Program

ABDC also learned from its own consultant that its SOM programs were inadequate. In 2014, seven years into the OMP, ABDC retained FTI Consulting, Inc. ("FTI") to assist the company with an assessment of its CSRA department in identifying critical gaps or areas for improvement.[178] FTI's investigation found numerous systemic issues with the staffing, roles, training, and direction provided for its compliance efforts.[179]

The systemic issues FTI found included *inter alia*, "ill-defined" roles which resulted in CSRA team members performing activities outside their purview, inadequate training and insufficient staffing with necessary resources or expertise, personnel overwhelmed by the volume of activities and demands of their position and lack of direction; compliance activities not occurring because responsibilities are unclear, perpetual state of reacting impeding ability to implement and sustain organization improvements; and the lack of a policy regarding which associate(s) at the distribution center are responsible for reviewing orders.[180] FTI also found ABDC failed to provide guidance or "visibility to the process and rationale for adjudicating orders held for review" and noted there is no standard set of defined reasons to support those decisions" regarding holding orders.[181]

The critical deficiencies that FTI highlighted point to an Order Monitoring Program incapable of maintaining effective controls to prevent diversion. ABDC's deficiencies in key areas such as staffing, training, and compliance efforts mean ABDC lacked any internal process or other

---

[178] 5/14 Trial Tr. (May) at 53:18-64:14, 67:20-25; P-00093 at 7.

[179] P-00093.

[180] *Id.* at 7-14.

[181] P-00472.

legitimate guardrails to reign in the volume of opioids it continued to dump into communities across the country. ABDC also elicited no testimony or documents at trial to indicate ABDC addressed the deficiencies described in FTI's report or made any changes at all in response to it.

C. ABDC Was Aware of the Devastating Effects of Its Failure to Maintain Effective Controls against Diversion

ABDC has also been well aware of the problems of opioid abuse and diversion and the ongoing opioid epidemic for years, further demonstrating the unreasonableness of its conduct. The members of ABDC's diversion control team were aware of the opioid crisis, opioid addiction, the relationship between pain pills and heroin. ABDC has admitted knowledge about the following:

- Based on information from the DEA, oxycontin "was a high risk for potential diversion" and necessitated closer scrutiny; [182]
- Recognized the public health dangers from diversion and abuse of controlled substances;[183]
- Viewed oxycontin and hydrocodone as high-risk drugs based in part upon monitoring drug abuse trends;[184]
- Had knowledge about interstate diversion from Florida, the Blue Highway and the Oxy Express;[185]
- Circulated email parodies regarding Pillbillies and Oxycontinville;[186]
- Had knowledge of huge quantity of hydrocodone purchases from illegal online pharmacies in Appalachia region;[187]

---

[182] Hazewski, 10/25/18 Depo at 61-62.

[183] 5/13 Trial Tr. (Zimmerman) at 135.

[184] 5/14 Trial Tr. (May) at 57-58.

[185] Hazewski, 10/25/18 Depo at 71-72 (Pill migration from Florida to West Virginia, Ohio and other states was "generally discussed information in the industry" and a red flag for diversion because a person with legitimate medical need would not travel out of state); *see also* 5/13 Trial Tr. (Zimmerman) at 84-90, 96-99 (ABDC Pillbillies emails; knowledge of heroin connection, knowledge of interstate diversion from Florida); *see also* Mash, 7/28/20 Depo at 81-82, 118 (discussed OxyExpress, diversion from Fla. through WV, during training to be ABDC VP of Sales in WV; cluster of out-of-state license plates at pharmacy store was red flag for sales people)

[186] P-00212; P-00217; 5/13 Trial Tr. (Zimmerman) at 84-90, 96-99.

[187] 5/13 Trial Tr. (Zimmerman) at 93.

- "there is a whole lot of pain in the Appalachia area"; [188] and
- opioids were being diverted and sold on the black market.[189]

By 2001 the United States Department of Justice ("DOJ") issued a warning about widespread diversion of Oxycontin and in 2003 the federal Government Accountability Office ("GAO") issued a report on the same subject, Prescription Drugs: Oxycontin Abuse and Diversion and Efforts to Address the Problem.[190]

ABDC was aware throughout the relevant period of not only the potential for, but the occurrence of, significant opioid diversion and misuse in West Virginia. In 2007, ABDC's Senior Vice President of Corporate Security & Regulatory Affairs, Chris Zimmerman, forwarded an article regarding rogue online pharmacies that were illegally dispensing hydrocodone and other prescription drugs, and acknowledged the issues of opioid abuse and diversion in Appalachia, writing: "Not only is this part of the country purchasing the majority of the hydrocodone from legitimate pharmacies, but they also buy a huge quantity from illegal on line [sic] pharmacies. There is a whole lot of pain in the Appalachia area."[191]

Mr. Zimmerman admitted that the Beverly Hillbillies parody that he forwarded in 2011 included an implicit recognition that there was pill migration from Florida up into Mountaineer land.[192] He was aware of the term "pillbillies" being used to describe "people that go down and pick up the drugs and then resell them."[193] In fact, he used the term himself when forwarding an email about Florida enacting opioid reforms stating "Watch out Georgia and Alabama. There will

[188] P-17051; 5/13 Trial Tr. (Zimmerman) at 93-94.

[189] P-17051.

[190] MC-WV-01764.

[191] P-17051; 5/13 Trial Tr. (Zimmerman) at 93.

[192] 5/13 Trial Tr. (Zimmerman) at 86- 90; P-17046.

[193] 5/13 Trial Tr (Zimmerman) at 90.

be a mass exodus of pillbillies heading north."[194] ABDC thus knew that diversion was occurring, but it continued to reap the profits of that diversion, rather take steps to control the distribution of the drugs it was selling.

VI. THE EVIDENCE SHOWS THAT ABDC'S DISTRIBUTION OF OPIOIDS INTO CABELL-HUNTINGTON VIOLATED THE CSA AND THE REQUIREMENT THAT ABDC PROVIDE "EFFECTIVE CONTROLS" AGAINST DIVERSION

The CSA requires distributors like ABDC to design and operate a system to identify suspicious orders of controlled substances (the "identification duty"); to report to the DEA suspicious orders when discovered (the "reporting duty"); and to decline to ship an order identified as suspicious unless and until, through due diligence, the registrant is able to determine that the order is not likely to be diverted into illegal channels (the "no-shipping duty").[195] The CSA defines suspicious orders to include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[196]

The evidence further shows that ABDC shipped suspicious orders of opioid products from 1996 through 2007 without conducting due diligence. Until 2007, ABDC relied on excessive order reports to identify and report suspicious orders. These excessive order reports were generated after the orders had already been shipped. The generation of these after-the-fact reports made it impossible for ABDC to comply with the no-shipping duty. Because the identified orders had already been shipped to their respective customers, it would have been impossible to conduct any due diligence on the orders identified on the excessive order reports prior to shipping.

---

[194] P-00282; 5/13 Trial Tr (Zimmerman) at 95-96.

[195] *See* 21 C.F.R. § 1301.74; *In re Nat'l Prescription Opiate Litig.*, 1:17-md-02804-DAP, 2019 WL 3917575 (N.D. Ohio Aug. 19, 2019); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206, 212-213 (D.C. Cir. 2017); *see also Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007).

[196] 21 C.F.R. § 1301.74(b).

ABDC did not have a policy to stop shipment of suspicious orders until 2007, after the DEA suspended its distribution license for a distribution center in Orlando, Florida for allegations of failing to maintain sufficient controls against diversion.

As evidenced by the sheer volume of opioids ABDC sent to local pharmacies, even after adopting its so-called enhanced diversion control program in 2007, ABDC continued to ship and distribute excessive amounts of opioids into Cabell-Huntington. ABDC set artificially high thresholds, continually increased thresholds for pharmacies without conducting due diligence, failed to obtain 590 forms on a substantial amount of its customers, and failed to maintain documentation that it conducted due diligence.

ARGUMENT

I. UNREASONABLE INTERFERENCE WITH A PUBLIC RIGHT CONSTITUTES A PUBLIC NUISANCE

West Virginia has adopted the definition of "public nuisance" set forth in § 821B of the Restatement (Second) of Torts ("Restatement"):[197] "A public nuisance is an unreasonable interference with a right common to the general public."[198] Thus, in West Virginia, the touchstone of public nuisance liability is unreasonableness.[199]

---

[197] *See Duff v. Morgantown Energy Assocs. (M.E.A.)*, 421 S.E.2d 253, 257 n.6 (W. Va. 1992); *Sharon Steel Corp. v. City of Fairmont*, 334 S.E.2d 616, 620 (W. Va. 1985); *State ex rel. Morrisey v. AmerisourceBergen Drug Corp.*, No. 12-C-141, 2014 WL 12814021, at *9 (W. Va. Cir. Ct. Dec. 12, 2014); *Rhodes v. E.I. du Pont de Nemours and Company*, 657 F.Supp.2d 751, 768 (S.D. W.Va. 2009); *Barker v. Naik,* No. 2:17-CV-04387, 2018 WL 3824376, at *3 (S.D.W. Va. Aug. 10, 2018) (Johnston, C.J.); see also *Callihan v. Surnaik Holdings of WV, LLC*, No. 2:17-CV-04386, 2018 WL 6313012, at *5 (S.D.W. Va. Dec. 3, 2018).

[198] RESTATEMENT § 821B(1) (1979).

[199] *See, e.g., Duff*, 421 S.E.2d at 262 (reasonableness of conduct determines whether conduct constitutes a nuisance); *West v. National Mines Corp*., 285 S.E.2d 670 (W. Va. 1981), *reh'g on appeal*, 336 S.E.2d 190 (W. Va. 1985) (activity must be reasonable to avoid liability for nuisance).

Both this Court and the Defendants recognize that unreasonableness is the applicable standard. This Court so held in its Memorandum Opinion and Order denying Defendants' motion for summary judgment regarding fault.[200] For the purposes of this motion, the Defendants have conceded that unreasonableness is the standard based on this ruling.[201] As set forth in detail above, the evidence at trial establishes that Plaintiffs have met this burden.[202]

II. PLAINTIFFS HAVE PROVEN THAT ABDC UNREASONABLY INTERFERED WITH PUBLIC RIGHTS

As described above, the evidence shows that ABDC's conduct was unreasonable in multiple ways. The conduct in question is the distribution of dangerously addictive narcotics with a high risk of diversion. Distributors like ABDC are uniquely able to act to prevent diversion because they know the quantity of opioids they are shipping to their customers within a particular region and can observe patterns of excessive or unusual ordering indicative of diversion at the pharmacies they supply. Nonetheless, ABDC acted unreasonably in failing to control the supply

[200] *See* April 29, 2021 Memorandum Opinion and Order, Dkt. 1294 at 6 (finding "Defendants have not established that there is a 'fault' element (in the way they describe it [intent, recklessness, or negligence]) of a public nuisance claim under West Virginia law."); *id.* ("The court agrees with plaintiffs that because defendants' motion does not establish the reasonableness of defendants' conduct, the motion should be denied.").

[201] ABDC's Brief at 6-7; Cardinal Health Brief at 5, n8; and McKesson Brief at 5.

[202] Even assuming *arguendo* that the Defendants are correct that an element of "fault" is required to prove the unreasonableness of their conduct, Dkt. 1294 at 6, the Plaintiffs have met the requirement as Defendants' conduct was intentional. In denying the Defendants' motions for summary judgment pertaining to fault, this Court held that "even assuming that there is a culpability ("fault") element in the public nuisance context, the motion should still be denied because there are disputed issues of material fact about whether defendants' conduct was intentional." Dkt. 1294 at 6 As the Court noted, Plaintiffs are not required to prove *mens rea* – or intent to create the opioid crisis or the resulting harms – only that their actions were intentional. Dkt. 1294 at 5-6. Here, the Plaintiffs proved that ABDC's conduct was an unreasonable interference based on its intentional selling and shipment of high volumes of opioids into Cabell-Huntington.

of opioids into Cabell-Huntington and failing to take reasonable steps to prevent diversion of these dangerous drugs.

ABDC acted unreasonably when it distributed an unreasonable quantity of opioids into Cabell and Huntington taking account the size of the population of the area into which these drugs were shipped and the scourge of addiction that emerged. It also acted unreasonably in operating its SOM programs: first, because the programs were not designed to detect suspicious orders at risk of being diverted; second, because the programs did not prevent ABDC from shipping orders it knew to be at risk of diversion; third because ABDC did not follow the programs it adopted, and fourth because ABDC knew about the harm its excessive shipments was causing and was repeatedly told what it needed to do in order to operate a proper SOMs program, but repeatedly failed to heed the guidance it was given. Finally, ABDC acted unreasonably with respect to the distribution of opioids when it failed to comply with the requirements of the CSA.

A. The Volume of Pills Shipped to Cabell and Huntington Proves Unreasonable Conduct

ABDC's distribution of an extraordinarily disproportionate quantity of opioids into Cabell and Huntington was unreasonable.[203] Despite ABDC's diversion control team's knowledge of the opioid crisis, opioid addiction, and the relationship between pain pills and heroin, ABDC distributed increasingly large amounts of opioids into Cabell-Huntington.[204]

ABDC distributed a total of 36 million dosage units of hydrocodone and oxycodone to pharmacies in Cabell-Huntington. Between June2002 and December of 2018, the equivalent of 360 doses for every man, woman, and child in the community, an amount that was, in and of itself, unreasonable and could not be explained by changes in the standard of care for treating pain.

[203] *See* The Evidence, §IV, *supra*,

[204] *See supra* Evidence §A.4, B.

In January 2006, ABDC's hydrocodone shipments to West Virginia doubled the national per pharmacy average.[205] From 2005 to 2016, ABDC shipped 248.16 million dosage units of oxycontin and hydrocodone to West Virginia.[206] From 2007 through 2018, there were 77,398 transactions by ABDC with pharmacies in Huntington-Cabell County, West Virginia.[207]

It was not only the overall volume of opioids they shipped to Huntington-Cabell, but the volume they sold to particular pharmacies that could only have been regarded as pill mills that should have alerted ABDC that they were fueling diversion.

The vast volume of opioids Defendants supplied to pharmacies in Huntington and Cabell County should have put Defendants on notice that they were not supplying a legitimate market for the drugs.[208] Yet, though Mr. Rannazzisi testified – and common sense dictates – that distributors should consider the volume of opioids it sells to a customer or area relative to its population, ABDC neither weighed these factors, or even totaled its shipments of opioids into a jurisdiction, in assessing whether orders were suspicious or diversion might be occurring.[209]

For instance , Drug Emporium #1, discussed above, is located in Barboursville in Cabell

---

[205] 5/18 Trial Tr. (Mays) at 117-18.

[206] Prevoznik, 5/17/19 Depo at 967-68.

[207] 5/26 Trial Tr. (Rafalski) at 103.

[208] Plaintiffs incorporate Plaintiffs' Memorandum of Law in Opposition to Defendants' Motions for Judgment on Partial Findings on Causation (Doc. No. 1469).

[209] 6/8 Trial Tr. (Rannazzisi) at 186 ("what we asked them to do is look at your suspicious – your pharmacy population, your customer population, identify anomalies within that population, ordering patterns, and then do your due diligence and see why those anomalies exist"); 5/17 Trial Tr. (Mays) at 203, 205 (between 2007 and 2014 the diversion control program did not rely on populations); Prevoznik, 5/17/19 Depo at 974 (DEA had said that knowledge of a geographic area's problem with controlled substance abuse is a factor that should be taken into account by registrants); *see also See* 5/26/21 Trial Tr. (Rafalski) at 112 (orders the Defendants knew or should have known were suspicious were likely to be diverted into the illicit market).

County. Barboursville had a 2010 population of 3,964.[210] ABDC shipped Drug Emporium #1 over 3.9 million doses of oxycodone and hydrocodone from 2006 through 2014 (based on ARCOS)—about 1,000 doses for every man, woman, and child.[211]

Huntington had a census population of 49,138 in 2010.[212] From January 2006 through February 2012, ABDC shipped SafeScript 3,888,340 doses of oxycodone and hydrocodone, or nearly 80 doses per person.[213]

These figures actually undercount the volume of opioids that reached Huntington and Cabell County. As detailed by James Rafalski, an additional wave of opioids were making their way into West Virginia from Florida and other states via a route often referred to as the "Oxy Express" or "Blue Highway."[214] ABDC's own documents acknowledge this migration, and ABDC circulated email parodies about Pillbillies and OxyContville, which described pill tourism to Florida.[215]

ABDC contends that the Plaintiffs have failed to provide evidence as to the "right" amount of prescription opioids that ABDC should have shipped to its customers in Cabell-Huntington.[216]

---

[210] ECF No. 1433-7.

[211] *See* 44711_00048 & ECF No. 1433-7 at p. 28.

[212] ECF No. 1433-7.

[213] P-44711_00044, P-43225_00001-6 & ECF No. 1433-7 at p. 28.

[214] 5/27 Trial Tr. (Rafalski) at 151-152 ("people that would get on airplanes in Huntington and fly to Florida to go to the pain clinics to get pills and then come back"; "Allegiant flight that was – they called it the Pill Express"); Mash, 7/28/2020 Depo at 81-82 (had heard of the Oxy Express coming from Florida through West Virginia); 5/13 Trial Tr. (Zimmerman) at 90-91.

[215] P-00217; P-00212.

[216] ABDC also claims that Mr. Rafalski's opinions that Defendants should have reported more orders and shipped fewer orders are not based in fact but is nothing more than *ipse dixit*. Plaintiffs incorporate Plaintiffs' Response to Memorandum in Support of Cardinal Health's Motion for Judgment. *See also* Dkt 1396 (Plaintiffs' Memorandum in Opposition to Defendants' Renewed *Daubert* Motion to Exclude The Opinions of James E. Rafalski).

But the "right amount" is irrelevant when the amount actually shipped was so clearly excessive in proportion to the local population. The "right amount" is also irrelevant when ABDC had actual knowledge that the enormous quantities of opioids it was shipping into Cabell and Huntington were being supplemented with *more* opioids that had been diverted from Florida. Whatever the "right amount" of opioids for Huntington and Cabell was, the quantities that ABDC shipped far exceeded it, and were unreasonable.

B. The Evidence Relating to ABDC's Diversion Control Program Establishes Unreasonable Conduct

As discussed in detail above, key deficiencies marred each of ABDC's diversion control programs. ABDC's diversion control programs were carried out nationally, through centralized compliance staff.

ABDC's programs for detecting "suspicious orders" of prescription opioids was not designed to, and could not, detect a significant percentage of orders that were sufficiently unusual in volume, pattern, or frequency to be indicative of diversion.[217] ABDC depended on monthly, volume-based thresholds for pharmacy customers as triggers for identifying potentially suspicious orders. By the time ABDC put thresholds in place, opioid sales and, thus, customer purchasing baselines had already been inflated by nearly a decade of diversion and excessive sales. Therefore, they were set too high, and offered no meaningful brake on suspicious orders.

ABDC failed to perform due diligence on opioid orders it knew were suspicious to determine if diversion was likely, shipped orders of prescription opioids it knew were suspicious without first ascertaining that those orders were not likely to be diverted, and continued shipping opioids to pharmacies that it knew showed indicia of diversion.[218]

---

[217] *See* The Evidence, §I, *supra*.

[218] *See* The Evidence, §II, *supra*.

ABDC failed to properly implement the suspicious order monitoring (SOMs) program that it did have.[219]

ABDC knew that its SOMs programs were inadequate, and knew the devastating effects of the failure to maintain controls against diversion, but failed to make changes to address the inadequacies.[220]

Mr. Rafalski testified that ABDC's systemic failures to maintain effective controls were a substantial factor in the diversion of prescription opioids into Cabell-Huntington.[221] He further testified that the orders ABDC knew or should have known were suspicious were likely to be diverted into Cabell-Huntington.

C. ABDC's Conduct Was Unreasonable Because it Violated the CSA

ABDC argues that violations of the federal CSA or West Virginia Controlled Substances Act (WVSCA) cannot provide the basis for Plaintiffs' public nuisance claims as neither contain private rights of action. Plaintiffs do not seek to enforce the CSA. Had ABDC and the other Defendants **merely** violated the CSA and not thereby created a nuisance or otherwise violated parallel common-law duties, Plaintiffs would have no claim. But Plaintiffs do not base their claim on a bare violation of the CSA.

---

[219] *See* The Evidence, §III, *supra*.

[220] *See* The Evidence, §V, *supra*.

[221] *See* The Evidence, §VI, *supra*.

Conduct that is unlawful is a basis for finding that an interference with a public right is unreasonable, and thus that a defendant may be found liable for creating or maintaining a nuisance.[222] Public nuisance liability may also be based on unlawful conduct, regardless of *mens rea*.[223]

That the unlawfulness of Defendants' conduct is relevant to whether that conduct constitutes or has created an unreasonable interference with a public right does not mean that Plaintiffs are seeking to enforce the CSA.

Indeed, it would make no sense for the Restatement to prescribe that a nuisance action may be predicated on the unlawfulness of the defendant's conduct if the only plaintiffs that could seek relief from the nuisance were those otherwise entitled to enforce the underlying statute. Nuisance actions are not so limited. Rather, as the Restatement makes clear, a public official or public agency representing a political subdivision may always bring an action to abate a nuisance.[224] Indeed, West Virginia specifically empowers Plaintiffs to sue to abate a nuisance.[225] This right to seek abatement is not limited based on the particular means of demonstrating that the interference with a public right is unreasonable. The additional element urged by Defendants, that the plaintiff must

---

[222] *See, e.g., Duff*, 421 S.E.2d at 262 (reasonableness of conduct determines whether conduct constitutes a nuisance); *West v. National Mines Corp*., 285 S.E.2d 670 (W. Va. 1981), *reh'g on appeal*, 336 S.E.2d 190 (W. Va. 1985) (activity must be reasonable to avoid liability for nuisance).

[223] *See, e.g.,* RESTATEMENT § 821B(2)(ii) (noting that circumstances "that may sustain a holding that an interference with a public right is unreasonable[,]" include "whether the conduct is proscribed by a statute, ordinance, or administrative regulation");[223] *West*, 285 S.E.2d at 676 (nuisance may arise from acts that are unlawful); *Morrisey,* 2014 WL 12814021, at *9 ("unreasonable interference" includes, *inter alia,* conduct that is contrary to a statute, ordinance, or regulation). West Virginia courts have rejected the argument that conduct **must** be unlawful in order to constitute a nuisance. *See Lemongello v. Will Co*., No. CIV.A. 02-C-2952, 2003 WL 21488208, at 2 (W. Va. Cir. Ct. June 19, 2003) (Berger, J.)

[224] RESTATEMENT § 821C; *see also id.* at cmt. j.

[225] *See* W.VA. CODE § 7-1-3kk; W.VA. CONST. art. 6, sec. 39a; W.VA. CODE § 8-12-2(8), (9-11).

also have the right to enforce the statute that rendered the defendant's conduct unreasonable by virtue of its unlawfulness, appears nowhere in the Restatement or in West Virginia law. It has simply been manufactured by Defendants.

ABDC relies on a single case involving indirect enforcement of statutes that do not provide for a private right of action, but that case is not on point and does not support ABDC's argument.[226] Plaintiffs are not suing Defendants, directly or indirectly, for violating the CSA. They are suing Defendants for having created a public nuisance. While the illegality of Defendants' conduct is a factor in whether they can be liable for that nuisance, it is the nuisance itself, and not the CSA violation, that gives rise to Plaintiffs' claims. Plaintiffs are no more enforcing the CSA than a RICO plaintiff is enforcing the underlying criminal statutes that constitute RICO predicate acts.

ABDC further claims that Plaintiffs have not established a violation of the CSA or WV CSA.[227] ABDC is incorrect – as described above, Plaintiffs have clearly established that ABDC

---

[226] *See* ABDC Br. at 39 (*citing Astra USA, Inc. v. Santa Clara Cty., Cal*., 563 U.S. 110, 118 (2011)). *Astra* involved the Public Health Services Act*,* which created price ceilings for drugs sold to certain health-care facilities, but provided no private right of action for those facilities to enforce the ceilings. *Id.* at 113. Drug manufacturers were, however, required, to sign a price "agreement" with the Secretary of Health and Human Services; the "agreement" included no negotiable terms and simply recited and recognized the manufacturers' responsibilities under the Act, including the price ceilings. *Id.* The Supreme Court in *Astra* rejected the health-care facilities' claim that they were third-party beneficiaries of the "agreements" and could sue for breach of contract to enforce those agreements. *Id.* at 113-14. The contractual claim rejected in *Astra* is wholly distinct from Plaintiffs' claims here. The Court in Astra refused to grant the plaintiffs third-party beneficiary status because doing so would have conflicted with a statutory scheme that gave enforcement power exclusively to the federal government and not to private parties. *Id.* at 121. This case is a public nuisance claim brought by governmental entities and neither federal nor state law preempts these claims. *See In re Nat'l Prescription Opiate Litig.,* 440 F.Supp.3d 773, 808 (N.D. Ohio 2020) (rejecting the Distributor Defendants' contention that "they are not subject to nuisance liability because their business activities are authorized and extensively regulated by state and federal law"); Dkt. 1285 at 7 (finding Defendants' state-law field preemption argument unavailing). The other cases cited by ABDC on this issue stand only for the anodyne proposition, not in dispute here, that private rights of action under federal statutes must be created by Congress.

[227] ABDC Brief at 38.

violated the CSA and WV CSA.

As discussed above, the CSA requires distributors to provide effective controls against diversion and imposes an identification duty – the duty to identify suspicious orders – a reporting duty – the duty to report suspicious orders to the DEA – and a no-shipping duty – the duty not to ship suspicious orders unless or until it is established through due diligence that the order is not likely to be diverted.[228] The WV CSA has corresponding duties. The West Virginia Controlled Substances Act ("WV CSA") is intended to be consistent with the federal CSA to the fullest extent practicable.[229] The WV CSA, adopted in 1971, is derived from the Uniform Controlled Substances Act of 1970 ("UCSA").[230] The UCSA, in turn, is similar to its federal counterpart, the CSA, and "was drafted to achieve uniformity between the laws of the several States and those of the Federal government.[231]

There can be no effective controls against diversion if a registrant is permitted to ship opioid orders it knows or should know bear the indicia of likely diversion. As the MDL Court explained, this last duty arises directly from the requirement to maintain effective controls against diversion set forth in 21 C.F.R. § 1301.71(a):

> [G]iven the overriding duty of a registrant to maintain effective controls against diversion, the Court is hard-pressed to think of a more basic requirement than not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels. How can a registrant freely ship suspicious orders and still comply with

---

[228] 21 C.F.R. § 1301.74(b).

[229] *See* W.Va. Code § 60A–6–603 [1971] (the UCSA "shall be so applied and construed as to effectuate its general purpose to make uniform the law with respect to the subject of this [Act] among those states which enact it."). The West Virginia Board of Pharmacy has adopted, by reference, the requirements of the federal regulations, 21 CFR Parts 1300-1321, and 21 U.S.C. 801. W. Va. C.S.R. § 15-2-2, superseded by W. Va. C.S.R. § 15-2-3 (Apr. 1, 2020).

[230] *State v. Young,* 185 W. Va. 327, 335, 406 S.E.2d 758, 766 (1991).

[231] *Id.* Uniform Controlled Substances Act of 1970 prefatory note, vol. 9, part II, *U.L.A.* 2 (1988).

> its duty to maintain controls against diversion? It cannot. It has a duty not to ship the order unless due diligence reasonably dispels the suspicion.[232]

On September 30, 2020, Judge Breyer, the federal district judge presiding over the case remanded from the MDL to the Northern District of California, adopted Judge Polster's conclusion on this point.[233] More recently, Judge White, the federal district judge presiding over the case remanded from the MDL to the Eastern District of Oklahoma, adopted Judge Polster's conclusion that "there is not only a duty to report suspicious orders once detected, but also a duty to either not fulfill those orders or to investigate them to determine that they are not likely to be diverted to illegal channels.[234]

The WV CSA provides that one of the qualifications for controlled substances licensure is that an applicant operate "in compliance with all federal legal requirements applicable to wholesale drug distribution."[235] Under the WV CSA, an applicant for a license to manufacture or distribute controlled substances is required to demonstrate that it provides "effective controls and procedures to guard against theft and diversion of controlled substances."[236]

The evidence presented at trial and outlined throughout this brief establishes that ABDC

---

[232] Opinion and Order Regarding Plaintiffs' Summary Judgment Motions Addressing the Controlled Substances Act, Dkt # 2483 at pp. 18-19.

[233] *See City and County of San Francisco v. Purdue Pharma L.P.*, No. 3:18-CV-07591-CRB, 2020 WL 5816488, at *4 (N.D. Cal. Sept. 30, 2020). Significantly, Judge Breyer held that the rulings of the MDL court were not binding on him, but were "highly persuasive authority to the extent that these decisions are consistent with California and Ninth Circuit authority." 2020 WL 5816488, at *2. He specifically found Judge Polster's ruling with respect to the duties of distributors under the CSA to be "persuasive." *Id.*

[234] *See The Cherokee Nation v. McKesson, et al*, No. CIV-18-056-RAW, Doc. # 288 at 9-10 (E.D. OK March 29, 2021).

[235] W. Va. Code § 60A-8-7(c)(1)(I).

[236] W. Va. C.S.R. § 15-2-4.2.1, superseded by W. Va. C.S.R. § 15-2-5.1.1 (Apr. 1, 2020).

clearly violated the CSA and WV CSA.[237] The volume of opioids shipped by ABDC, the lack of controls to identify and stop suspicious orders, and their intentional disregard of what few procedures they had to protect the public each clearly establish statutory and regulatory violations. Such violations of the law are sufficient to allow the Court to conclude that ABDC acted unreasonably.

CONCLUSION

For all of the reasons set forth, this Court should deny ABDC Drug Corporation's Motion for Judgment Under Rule 52(c).

Dated: July 25, 2021

Respectfully submitted,

THE CITY OF HUNTINGTON
/s/ *Anne McGinness Kearse*
Anne McGinness Kearse
WVSB No. 12547
Joseph F. Rice
MOTLEY RICE LLC
28 Bridgeside Blvd.
Mount Pleasant, SC 29464
Tel: 843-216-9000
Fax: 843-216-9450
akearse@motleyrice.com
jrice@motleyrice.com

Linda Singer
David I. Ackerman
MOTLEY RICE LLC
401 9th Street NW, Suite 1001
Washington, DC 20004
Tel: 202-232-5504
Fax: 202-386-9622
lsinger@motleyrice.com
dackerman@motleyrice.com

CABELL COUNTY COMMISSION
/s/ *Paul T. Farrell, Jr.*
Paul T. Farrell, Jr.
WVSB Bar No. 7443
FARRELL & FULLER LLC
1311 Ponce de Leon Ave., Suite 202
San Juan, Puerto Rico 00907
Mobile: 304-654-8281
paul@farrell.law

/s/ *Anthony J. Majestro*
Anthony J. Majestro
WVSB No. 5165
POWELL & MAJESTRO, PLLC
405 Capitol Street, Suite P-1200
Charleston, WV 25301
304-346-2889 / 304-346-2895 (f)
amajestro@powellmajestro.com

[237] *See* The Evidence, §VII, *supra*.

Charles R. "Rusty" Webb
WV No. 4782
THE WEBB LAW CENTRE
716 Lee Street, East
Charleston, West Virginia 25301
Telephone: (304) 344-9322
Facsimile: (304) 344-1157
rusty@rustywebb.com

Michael A. Woelfel
WVSB No. 4106
WOELFEL AND WOELFEL, LLP
801 Eighth Street
Huntington, West Virginia 25701
Tel. 304.522.6249
Fax. 304.522.9282
mikewoelfel3@gmail.com

CERTIFICATE OF SERVICE

I certify that on July 25, 2021, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system.

/s/ *Anthony J. Majestro*